UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,336	07/11/2003	Soldano Ferrone	03551.0135	9015

26712 7590 03/10/2005

HODGSON RUSS LLP
ONE M & T PLAZA
SUITE 2000
BUFFALO, NY 14203-2391

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,336	FERRONE ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3-7 and 9-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The response filed on January 31, 2005 to the restriction requirement of December 27, 2004 has been received. Applicants have elected Group I, claim(s) 1-8 and 16-19, as specifically drawn to an isolated peptide which blocks the binding of an anti-GD3 antibody to a tumor cell expressing GD3 ganglioside.

Applicant's election with traverse of Group I, claim(s) 1-8 and 16-19, is acknowledged. The traversal of the restriction requirement is on grounds that a search for the six listed peptides should not be unduly burdensome on the Examiner. This argument has been considered but is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the restriction requirement of December 27, 2004.

As to the question of burden of search, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of six different polypeptides, and different polypeptide segments in the databases would require extensive searching and review.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Note: In the response file on January 31, 2005, Applicant interpreted the election of a ONE polypeptide SEQ ID NO: as an election of species and not an election of an invention. A telephone call was made to Ranjana Kadle on February 25, 2005 to request an oral election of ONE polypeptide SEQ ID NO: as the invention. Applicants thereby elected SEQ ID NO: 6. Applicant in replying to this Office action must make affirmation of this election.

Claims 1-19 are currently pending.

Claims 3-7 and 9-15 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1-2, 8 and 16-19 are currently under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on April 26, 2004 is acknowledged and has been considered. A signed copy of the IDS is attached hereto.

In addition, the listing of references in the specification, page 18, line 6 to page 20, line 7, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The specification is objected to on page 11, line 5 for improper disclosure of a nucleotide sequence without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Claim Objections

Claims 2 (8) and 18 (19) are objected to because of the following informalities: Claims 2 and 18 are drawn to non-elected inventions, i.e., SEQ ID NOs: 1, 2, 3, 4 and 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishikawa *et al.* (WO 01/81371 A1, 2001 as evidenced by EP 1279677, 2003 for English Translation).

In the instant case, claim 1 is drawn to an isolated and purified peptide which blocks the binding of anti-GD3 antibody to a tumor cell expressing GD3 ganglioside and is capable of eliciting antibodies reactive against CD3 ganglioside. Claims 16 is drawn to an antigenic composition comprising a peptide which blocks the binding of an anti-GD3 antibody to a tumor cell bearing GD3 ganglioside and is capable of eliciting antibodies reactive against GD3 ganglioside and a pharmaceutically acceptable carrier. The antigenic composition of claim 16 is further comprises an adjuvant (claim 17).

Ishikawa *et al.* disclose GD3-mimetic peptides. Specifically, the WIPO application teaches isolated and purified GD3-mimetic peptides which achieve specific binding to an anti-GD3 antibody and medicinal compositions containing the same (abstract). Ishikawa *et al.* further provide antigenic compositions comprising a pharmaceutical carrier with a GD3 peptide mimetic that binds to an anti-GD3 antibody (page 8, paragraph 0092 of EP document) and also, antigenic compositions comprising a pharmaceutical carrier with a GD3 peptide mimetic that is capable of eliciting antibodies reactive against GD3 ganglioside (page 9, paragraphs 0093 to 0094 of EP document). Furthermore, Ishikawa et al. disclose that the antigenic compositions may further comprise an adjuvant (page 10, paragraph 0109 of EP document). Although the reference does not specifically teach that the purified peptide blocks the binding of anti-GC3 antibody to a tumor cell expressing GD3 ganglioside, the claims are drawn to the product *per se* and inherently, such a polypeptide that binds specifically to an anti-GD3 antibody would block the binding of anti-GD3 antibody to a tumor cell expressing GD3 ganglioside. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed

in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrone, S (WO 00/38515, 2000).

Ferrone discloses peptide mimics useful for treating diseases. Specifically, the WIPO application teaches isolated and purified peptide mimetics which are recognized by anti-GD3 ganglioside mAb (page 31, *Example 3*). Ferrone further provides that the GD3 peptide mimetic were cable of eliciting antibodies reactive against GD3 ganglioside (page 32, *Immunogenicity in BALB/c mice*). Moreover, the WIPO document provides a "vehicle" by which the peptide mimetic can be presented to an immune system, wherein an antigenic composition comprises the peptide mimetic and a pharmaceutical carrier or an adjuvant (page 11, 5th paragraph). Although the reference does not specifically teach that the purified peptide blocks the binding of anti-GC3 antibody to a tumor cell expressing GD3 ganglioside, the claims are drawn to the product *per se* and inherently, such a polypeptide that binds specifically to an anti-GD3 antibody would block the binding of anti-GD3 antibody to a tumor cell expressing GD3 ganglioside. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The following prior art is provided and made of record (although not relied upon) is considered pertinent to applicant's disclosure:

Willers et al. (Peptides 1999; 20: 1021-1026).

Note: There is no prior art that teaches or suggests a peptide consisting of SEQ ID NO: 6. The closest prior art is Ishikawa *et al* and Ferrone, whom teach, as applied to claims 1 and 16-17 above, peptide mimetics which are recognized by anti-GD3 ganglioside mAb. Thus, claims 2, 8 and 18-19 are free of the prior art but are rejected as being drawn to a rejected dependent base claim.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/7/05